

§ 172.120

21 CFR Ch. I (4–1–02 Edition)

§ 172.120 Calcium disodium EDTA.

The food additive calcium disodium EDTA (calcium disodium ethylenediaminetetraacetate) may be safely used in designated foods for the purposes and in accordance with the conditions prescribed, as follows:

(a) The additive contains a minimum of 99 percent by weight of either the dihydrate $C_{10}H_{12}O_8N_2CaNa_2 \cdot 2H_2O$ or the trihydrate $C_{10}H_{12}O_8N_2CaNa_2 \cdot 3H_2O$, or any mixture of the two.

(b) It is used or intended for use as follows:

(1) Alone, in the following foods at not to exceed the levels prescribed, calculated as the anhydrous compound:

Food	Limitation (parts per million)	Use
Cabbage, pickled	220	Promote color, flavor, and texture retention.
Canned carbonated soft drinks .	33	Promote flavor retention.
Canned white potatoes	110	Promote color retention.
Clams (cooked canned)	340	Promote color retention.
Crabmeat (cooked canned) .	275	Retard struvite formation; promote color retention.
Cucumbers pickled	220	Promote color, flavor, and texture retention.
Distilled alcoholic beverages .	25	Promote stability of color, flavor, and/or product clarity.
Dressings, nonstandardized .	75	Preservative.
Dried lima beans (cooked canned) .	310	Promote color retention.
Egg product that is hard-cooked and consists, in a cylindrical shape, of egg white with an inner core of egg yolk .	1200	Preservative.
Fermented malt beverages .	25	Antigushing agent.
French dressing	75	Preservative.
Legumes (all cooked canned, other than dried lima beans, pink beans, and red beans) .	365	Promote color retention.
Mayonnaise	75	Do.
Mushrooms (cooked canned) .	200	Promote color retention.
Oleomargarine	75	Preservative.
Pecan pie filling	100	Promote color retention.
Pink beans (cooked canned) .	165	Promote color retention.
Potato salad	100	Preservative.
Processed dry pinto beans .	800	Promote color retention.
Red beans (cooked canned) .	165	Promote color retention.
Salad dressing	75	Preservative.
Sandwich spread	100	Do.
Sauces	75	Do.

Food	Limitation (parts per million)	Use
Shrimp (cooked canned) .	250	Retard struvite formation; promote color retention.
Spice extractives in soluble carriers .	60	Promote color and flavor retention.
Spreads, artificially colored and lemon-flavored or orange-flavored .	100	Promote color retention.

¹ By weight of egg yolk portion.

(2) With disodium EDTA (disodium ethylenediaminetetraacetate) in the following foods at not to exceed, in combination, the levels prescribed, calculated as anhydrous $C_{10}H_{12}O_8N_2CaNa_2$:

Food	Limitation (parts per million)	Use
Dressings, nonstandardized	75	Preservative.
French dressing	75	Do.
Mayonnaise	75	Do.
Salad dressing	75	Do.
Sandwich spread	100	Do.
Sauces	75	Do.

(c) To assure safe use of the additive:

(1) The label and labeling of the additive container shall bear, in addition to the other information required by the Act, the name of the additive.

(2) The label or labeling of the additive container shall bear adequate use directions to provide a final food product that complies with the limitations provided in paragraph (b) of this section.

(d) In the standardized foods listed in paragraph (b) of this section, the additives are used only in compliance with the applicable standards of identity for such foods.

[42 FR 14491, Mar. 15, 1977, as amended at 48 FR 10815, Mar. 15, 1983; 58 FR 52222, Oct. 7, 1993; 60 FR 33710, June 29, 1995; 65 FR 48379, Aug. 8, 2000]

§ 172.130 Dehydroacetic acid.

The food additive dehydroacetic acid and/or its sodium salt may be safely used in accordance with the following prescribed conditions:

(a) The food additive meets the following specifications:

Dehydroacetic acid: Melting point, 109 °C–111 °C; assay, minimum 98 percent (dry basis).

Sodium salt of dehydroacetic acid: Assay, minimum 98 percent (dry basis).

(b) It is used or intended for use as a preservative for cut or peeled squash, and is so used that no more than 65 parts per million expressed as dehydroacetic acid remains in or on the prepared squash.

(c) The label or labeling of any package of the additive intended for use in food shall bear adequate directions for use to insure compliance with this section.

§ 172.133 Dimethyl dicarbonate.

Dimethyl dicarbonate (CAS Reg. No. 4525-33-1) may be safely used in food in accordance with the following prescribed conditions:

(a) The additive meets the following specifications:

(1) The additive has a purity of not less than 99.8 percent as determined by the following titration method:

PRINCIPLES OF METHOD

Dimethyl dicarbonate (DMDC) is mixed with excess diisobutylamine with which it reacts quantitatively. The excess amine is backtitrated with acid.

APPARATUS

250-milliliter (mL) Beaker
100-mL Graduate cylinder
25-mL Pipette
10-mL Burette (automatic, eg., Metrohm burette)
Stirrer
Device for potentiometric titration
Reference electrode
Glass electrode

REAGENTS

Acetone, analytical-grade
Solution of 1 N diisobutylamine in chlorobenzene, distilled
1 N Acetic Acid

PROCEDURE

Accurately weigh in about 2 grams of the sample (W) and dissolve in 100 mL acetone. Add accurately 25 mL of the 1 N diisobutylamine solution by pipette and allow to stand for 5 minutes. Subsequently, titrate the reaction mixture potentiometrically with 1 N hydrochloric acid (consumption=a mL) while stirring. For determining the blank consumption, carry out the analysis without a sample (consumption=b mL).

CALCULATION

$$\frac{(b-a) \times 13.4}{W} = \% \text{ DMDC}$$

NOTE: For adding the diisobutylamine solution, always use the same pipette and wait for a further three drops to fall when the flow has stopped.

(2) The additive contains not more than 2,000 ppm (0.2 percent) dimethyl carbonate as determined by a method entitled "Gas Chromatography Method for Dimethyl Carbonate Impurity in Dimethyl Dicarbonate," which is incorporated by reference in accordance with 5 U.S.C. 552(a). Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(b) The additive is used or intended for use as a microbial control agent in the following beverages under normal circumstances of bottling, canning, or other forms of final packaging, where the viable microbial load has been reduced to 500 microorganisms per milliliter or less by current good manufacturing practices such as heat treatment, filtration, or other technologies prior to the use of dimethyl dicarbonate:

(1) In wine, dealcoholized wine, and low alcohol wine in an amount not to exceed 200 parts per million.

(2) In ready-to-drink teas in an amount not to exceed 250 parts per million. unflavored beverages containing added electrolytes (5-20 milliequivalents/liter sodium ion (Na+) and 3-7 milliequivalents/liter potassium ion (K+)) in an amount not to exceed 250 parts per million.

(4) In carbonated, dilute beverages containing juice, fruit flavor, or both, with juice content not to exceed 50 percent, in an amount not to exceed 250 parts per million.

(c) To ensure the safe use of the food additive, the label of the package containing the additive shall bear, in addition to other information required by the Federal Food, Drug, and Cosmetic Act: